OCULUS SDI 4

INSTRUCTION MANUAL

Stereoscopic **D**iagonal **I**nverter

OCULUS®

Notes on this instruction manual

Thank you for your purchase and the trust you have placed in this OCULUS products. The SDI 4 has been manufactured and tested according to strict quality criteria. You have selected a modern and well-engineered product.

The stereoscopic diagonal inverter, SDI 4, is an advanced development of the SDI.

To ensure safe operation, it is essential that you use the device correctly. For this reason you should familiarise yourself thoroughly with the contents of this instruction manual before operating the device. In particular, pay attention to the safety instructions.

This operating manual describes the following SDI 4 models:

- SDI 4c
- SDI 4e
- SDI 4m

Due to ongoing development, the diagrams shown in the instruction manual may depict minor changes to the actual device delivered.

If you have any queries or would like additional information about your device, do not hesitate to call or send us a fax. Our service team will gladly assist.

OCULUS Optikgeräte GmbH

Management and workers

OCULUS is certified according to DIN EN ISO 9001:2000 and 13485:2003, setting high standards of quality where development, manufacture, quality assurance and service regarding the entire range of products are concerned.

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1 Scope of Delivery

SDI 4

Models	
■ SDI 4m with two protective dust covers and securing device	54302
■ SDI 4m (Leica version) with two protective dust covers and securing device	54312
■ SDI 4e with two protective dust covers and securing device	54300
■ SDI 4e (Leica version) with two protective dust covers and securing device	54310
■ SDI 4c with two protective dust covers and securing device	54320
■ SDI 4c (Leica version) with two protective dust covers and securing device	54330

Components for each SDI 4
■ Sterilizable rubber cap
■ Hexagon screw driver
■ Plastic carrying case with liners
■ Instruction manual
■ Conditioning manual of Oculus Optikgeräte GmbH

Components for SDI 4c and SDI 4e
■ For SDI 4e only: Hand-held pushbutton
■ For SDI 4c only: Steam autoclave cable duct

Note

We reserve the right to change the scope of delivery in line with ongoing technical development.

2 Safety Instructions

2.1 Pictogram definitions

Attention

Indicates a potentially hazardous situation that can result in injury or material damage.

Note

Instructions for use, and useful or important information.

2.2 Safety instructions concerning organisation

The law requires that the manufacturer expressly informs the user about safety aspects concerning the handling of the SDI 4. This chapter contains a summary of the most important safety-related information.

Attention

Do not operate the unit until you have read and fully understood the entire operating instructions.

- ➔ Make sure to keep this instruction manual in a safe place and available to operating personnel at all times.
- ➔ Observe the legal regulations with regard to accident prevention.
- ➔ The unit must not be used if a fault occurs that you cannot rectify. Get in touch with our service personnel.

Attention

Heed unconditionally the operating instructions and safety advice of the operating microscope and of the additional equipment. Familiarize yourself with all safety features and devices before you put the unit into initial operation.

2.3 Safety instructions for use of the SDI 4

Note

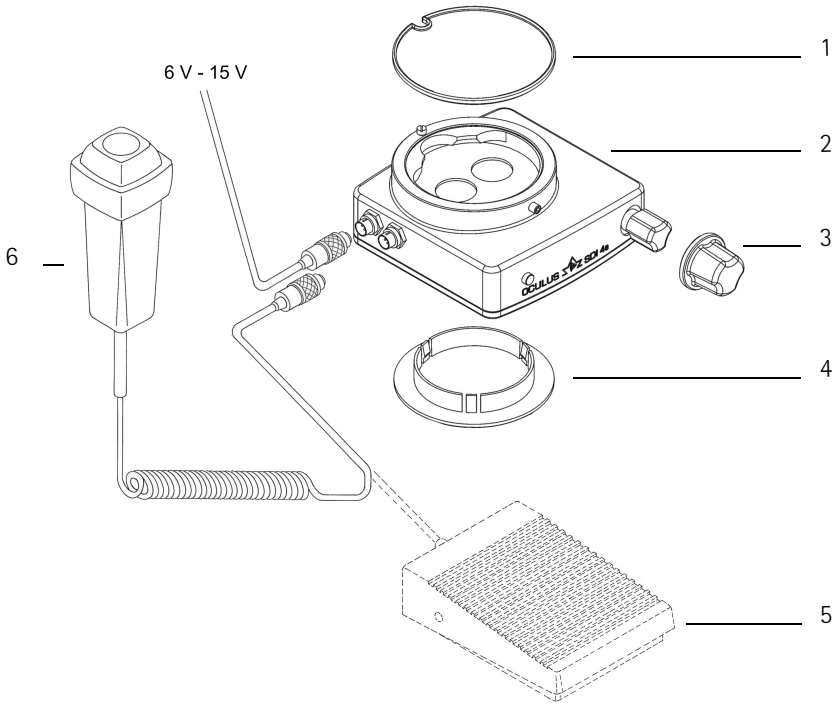
Before putting the SDI 4 into operation for the first time, the user must be familiarized with it by an Oculus Optikgeräte GmbH representative or an authorized dealer.

Attention

No modifications may be made to this device without the permission of the manufacturer.

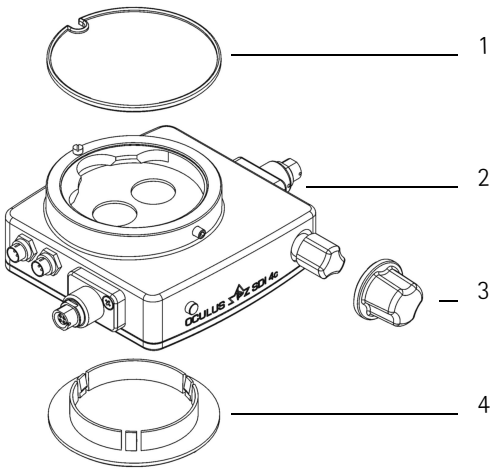
- Only operate the device using original accessory parts supplied by us, and when the device is in technically correct working order.
- Do not use the unit if it is damaged; in this case, get in touch with your supplier.
- Observe the legal regulations with regard to accident prevention.
- Also comply with the legal provisions in force in your country, and with the hygiene and waste disposal regulations of the hospital or clinic.
- If a fault occurs that you cannot rectify with the help of the troubleshooting table *(sect. 10, page 14)*, the unit must not be used! Clearly mark the unit as non-operational and get in touch with our service personnel.
- The sterilizable rubber cap of the adjustment knob of the SDI 4 is to be sterilized before the first and each further application.
- It is imperative that you heed the cleaning, disinfection and sterilization instructions given in the conditioning manual.

3 Device Description



1 Dust cover
2 SDI 4e
3 Sterilizable rubber cap
4 Dust cover
5 Foot switch
6 Hand switch

fig. 3-1: Desription SDI 4e



1 Dust cover
2 SDI 4c
3 Sterilizable rubber cap
4 Dust cover

fig. 3-2: Description SDI 4c

4 Functional Description

The SDI 4 (Stereoscopic Diagonal Inverter) before you reinverts images, e.g. that of a BIOM 4 or a wide angle contact lens.

SDI 4e/4c

The image inversion provided by the SDI 4e/4c can be turned on and off via a hand-held pushbutton or an optional foot switch in less than a second.

If electrical adjustment is impossible for any reason, you also have the option of aligning the optic system mechanically by hand with the adjustment knob.

You can recognize the position of the optical system by the indicator light. If it is yellow, the image inversion feature is activated.

If adjusting mechanically by hand, turn the adjustment knob clockwise until you feel it click into position. The indicator lights up shortly before the final position is reached.

Only SDI 4c

If the SDI 4c is used together with the BIOM 4c, the image inverter is controlled by the position of the BIOM 4c. A position switch on board of the BIOM 4c activates the SDI 4c, while being swung into the vertical working position.

If the BIOM 4c is out of the beam path, the SDI 4c is automatically switched off. Independently the SDI 4c can be controlled via the combi- foot switch.

SDI 4m

Image erection with the SDI 4m can take place only by mechanical adjustment with the hand-turned knob. You can recognize the position of the optical system by the indicator in the transparent glass. It is centrally located on the front of the SDI 4m, just to the left of the adjustment knob. If the transparent indicator is completely yellow, this means that the image inversion is not taking place at the moment.

5 Proper Usage

These stereoscopic diagonal inverters SDI 4m/4e/4c reverse the picture of indirect monitoring systems (BIOM 4, wide-angle contact lenses) true to during minimal invasive posterior segment surgery of the human eye.

The device should be used only by physicians and OP personnel who have been correspondingly trained and who have the training, knowledge, and practical experience to ensure appropriate handling.

The SDI 4 is intended for use with correspondingly designed surgical microscopes in hospitals, clinics or other places where human medicine is practiced.

Such surgical microscopes must be specifically designated by OCULUS Optikgeraete GmbH as being compatible.

Only operate the device using original accessory parts supplied by OCULUS Optikgeraete GmbH , and when the device is in technically correct working order.

Use only the net plug adapter from OCULUS Optikgeraete GmbH as a power supply unit. If the microscope has sockets designated by the microscope support manufacturer as conforming to IEC-601, these may also be used.

Please also heed to safety instructions listed above.

6 Operation

6.1 Preliminary steps

Please remove the plastic carrying case from its packing and dispose of the packing properly.

The sterilizable rubber cap is to be cleaned, disinfected and sterilized before the first and each further application.

Please keep the plastic carrying case and the securing device in a safe place even after the unit has been assembled, since subsequent longterm storage or return for servicing or repairs as well as shipment of the unit can best take place only in the plastic carrying case with its special lining and the securing device.

As part of an optical unit, the SDI 4, like the surgical microscope, should be handled with care and should not be subjected to shocks, blows, soiling or high temperatures (above 40° C).

Before assembling the unit, remove both protective dust covers and the securing device. The upper protective dust cover can be removed by unscrewing the hexagon socket set screw, and the lower one can be simply pulled downwards. Store these as well for best subsequent dust protection should you disassemble the SDI 4 at a later date.

6.2 Attachment to an operating microscope

Note

It is advisable that two persons carry out the installation or the dismantling of the SDI 4 at an operation microscope.

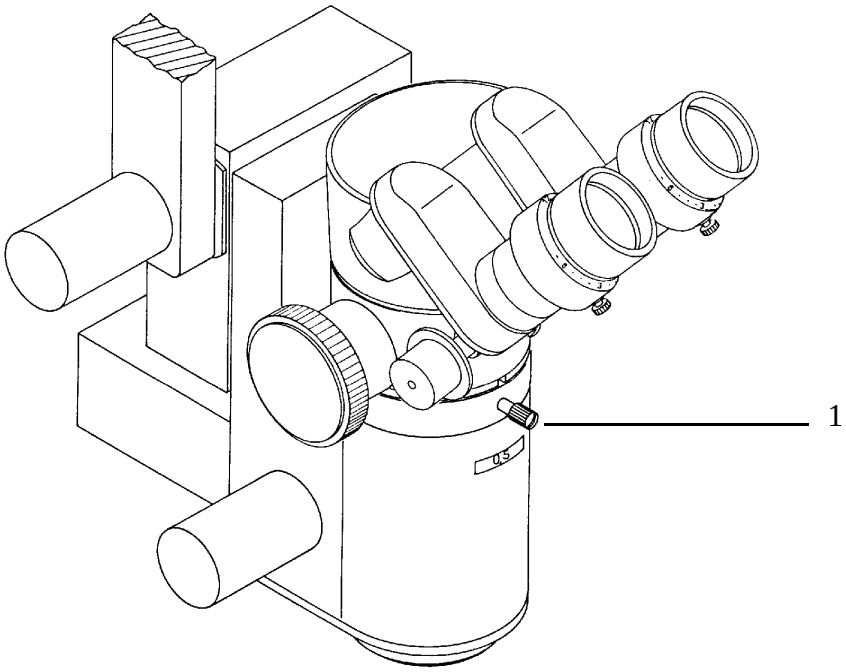


fig. 6-1: Before the installation of the SDI 4

1 Locking screw

- ➔ Always take care when mounting or removing the SDI 4 that none of the optics in the beam paths become soiled.
- ➔ Whilst protecting the binocular tube from falling down, please unscrew the locking screw on the main body of the microscope (1).
- ➔ Typically, the SDI 4 is mounted below the beam splitter.

  Remove the binocular eyepiece and the beam splitter from the main body of the microscope.

  On some microscopes the beam splitter is permanently built into the microscope; in this case, the SDI 4 must be mounted above the beam splitter.

- ➔ Now place the flange of the SDI 4 into the dovetail receptacle of the main body of the microscope. Check that the SDI 4 is properly seated before carefully tightening the locking screw of the main body of the microscope. When properly mounted, the SDI 4 should not wobble.

  Please make sure of this before attaching the other microscope components.

➔ Proceed in the same manner when mounting the beam splitter, the binocular eyepiece and other components of the microscope;
that is, carefully tighten the hexagon socket set screw of the SDI 4 *(fig. 6-2, page 9, position 1)* in the same way with the included hexagon screw driver and then make sure that each component is correctly seated.
If an endolaser is used, the laser shutter can be positioned either between the main body of the microscope and the SDI 4 or between the SDI 4 and the beam splitter.
In order to protect surgeon and assistants from the laser light, the laser filter is to be installed below the beam splitter used.

Attention

If the laser filter can only be used **above** the beam splitter or if a stereo,-0°- binocular microscope is used, a separate eye protection is to be provided for the assistant.
No SDI of the company Oculus OCULUS Optikgeraete GmbH has an integrated laser protection filter.

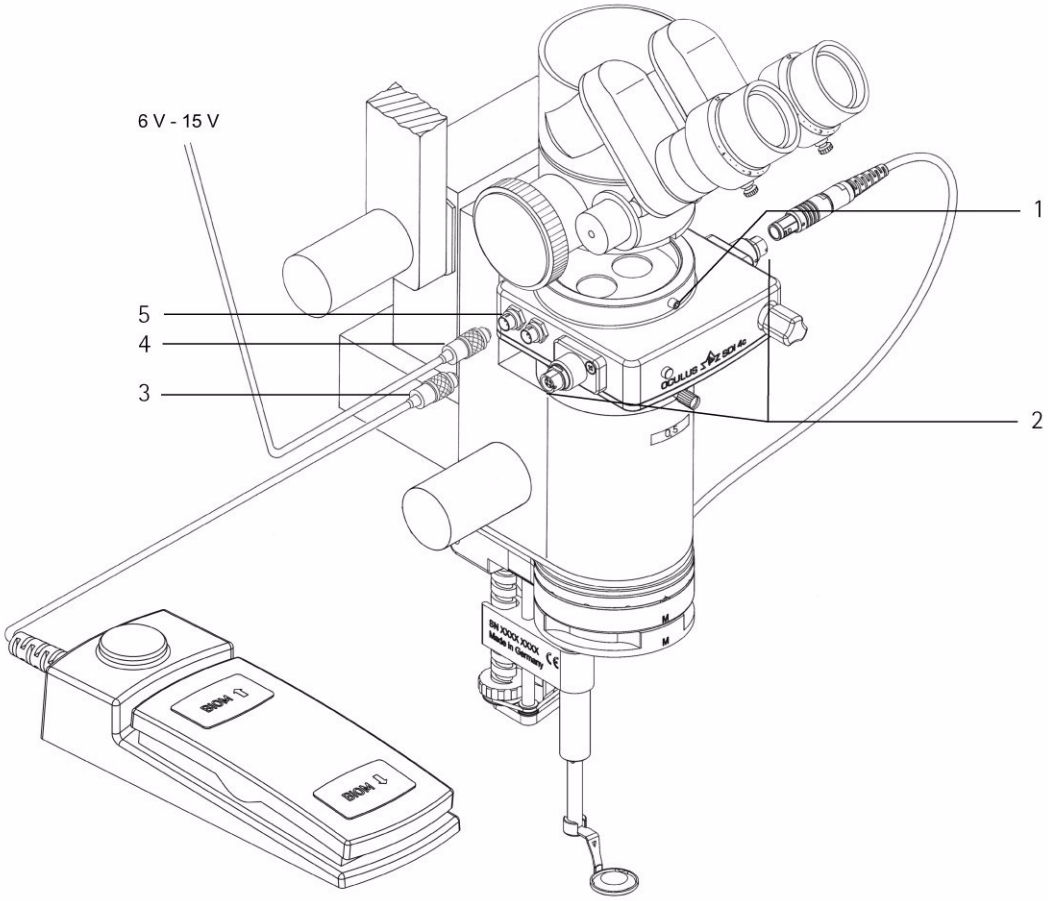
➔ When using a laser, always follow the instructions in its instruction manual.
➔ Before connecting the electrical versions of the SDI 4 to the power supply, check to see whether the power supply voltage is within the voltage range given on the rating plate. This is always the case if the plug-in transformer from OCULUS Optikgeraete GmbH is used. Please ensure that the power supply voltage of the mains socket lies within the voltage range of the net plug adapter.
➔ When connecting the hand or foot switch, please do not join the electrical plug-and-socket connections by excessive force.
If you are unable to make a plug connection, check whether the plug fits the socket. If you detect damage to the connection, you should contact our service personnel.
➔ After inserting the plugs into the corresponding sockets *(fig. 6-2, page 9, position 5)*, lock it in place by turning the threaded connector (milled sleeve).

Connector SDI 4c

➔ Observe the proper alignment of plugs and sockets on the left side of the SDI 4c.
➔ The plug of the combination control panel is connected to the foremost 5-pin socket of the two sockets that can be found directly in the SDI 4 housing.
➔ The power supply plug (6V-15V) is connected to the rear 3-pin socket.
➔ Once the plugs are connected, they are to be secured by turning the knurled screw.
➔ The 4-pin sockets projecting from an extension are used to connect the BIOM 4c (only the SDI 4c (Leica) is equipped with rotating connection sockets).

Attention

SDI 4c has 4-pin sockets for connection with BIOM 4c only. The older version BIOM 3c cannot be connected or used with SDI 4c.



1 *Hexagon socket set screw*
2 *Sockets for connection with BIOM 4c*
3 *Connection with combi foot switch*
4 *Connection with net plug adapter*
5 *Correspondending sockets*

fig. 6-2: SDI 4c / BIOM 4c and possible connections

7 Transport of the SDI 4

- Avoid impacts when moving the SDI 4 to another location, since this can have an adverse affect on the adjustments.
- Only with the use of the securing device you position the optical system of the SDI 4 in the rest position.
- Check the unit and its accessories for damage after every transport.
- Do not keep the unit in a vehicle before use during the cold months of the year: the unit's optics can become fogged following wide-ranging changes in temperature from cold to warm.

  Should this occur, however, please give the unit time to adapt to the conditions of its new location before putting it into operation.

8 Operation

8.1 Prior to each use

Before each use, check that

- the unit is in technically perfect condition
- all connections and fasteners that can be loosened are properly tightened and are in a safe condition
- all cables and plugs are free of damage
- the unit is connected to a proper power supply (SDI 4c and SDI 4e)
- all electric functions are operational:
  SDI on/off (SDI 4e, 4c)
  BIOM-focusing up, BIOM-focusing down (SDI 4c)
- the rubber cap for the adjustment button of the SDI 4c is supplied and sterile

Please adjust the inclinable binocular tube in a way, that you sit most comfortably.

8.2 Practical tips on using the SDI 4

For the shift of the optical system of the SDI 4 activate the foot switch by pressing it briefly. The optic system then moves to its other position.

Always activate the SDI 4 if you are using BIOM 4 or an indirect vitrectomy lens.

When activated, the indicator light of the SDI 4c and SDI 4e.
The indicator remains empty on the SDI 4m.

If you are using non-inverting optics, like for instance a Kilp contact-lens or if you have the BIOM swivelled out, the inverting function of the SDI 4 is to be de-activated. The indicator light of the SDI 4c and SDI 4e is not illuminated in this case, and is yellow on the SDI 4m and showing "0".

Installment of the SDI 4 lengthens the microscope tube only insignificantly, so that it can remain on the superstructure of the microscope even during anterior eye segment operations or cataract surgery. Please make sure that then the SDI 4 is deacitvated.

8.3 Practical tips on using wide-angle contact lenses

Attention

If you are also using a BIOM always make sure that it is swung to the side when you use the contact lens.

After the anterior third of the vitreous has been removed and you cannot gain a deeper view with normal microscope observation, a contact lens gives a good view onto the retina.

Turn off the coaxial, oblique illumination of the microscope, since this can lead to undesirable reflections when a BIOM or a contact lens is used.

Check the position of the instruments repeatedly during the operation, since it is very difficult to recognize the patient's crystalline lens through the contact lens (risk of lens touch).

In order to focus the microscope, using a wide field contact lens, set it to lowest magnification and then raise it a bit (away from the eye) by using the focus function at the foot switch.

Work at the lowest suitable microscope magnification. Most surgeons spontaneously reduce magnification after they become familiar with the unit in order to achieve a larger field of view.

When using contact lenses, remember to use an appropriate contact solution and to renew it if the view into the eye deteriorates.

Take care that the vitrectomy lens is well seated when using it. If the assistant complains of a poor view, although you find the image good (or vice versa), it is possible that only one observation beam path of the microscope is receiving and transmitting a good image. Slightly shifting the lens will correct this problem.

There is practically no need to move the patient's eye for a view of the fundus periphery when a wide-angle contact lens is used.

You can bring the ora serrata into view by tilting the contact lens a little or by shifting it horizontally.

Many wide-angle contact lenses possess enormous depth of field. The concavity of the fundus then appears slightly flattened, especially toward the periphery. It is also possible that the anterior parts of intraocular instruments will at first appear somewhat thicker and slightly bent.

When using a wide-angle contact lens keep fiber endoillumination as far as possible from the retina. This way you can reach a maximum light cone at low light exposure on the retina. This utilizes the wide-angle effect of the lens to the full.

Panoramic illumination systems like MIS (Multiport Illuminations System) or chandelier illumination give optimum illumination with even less retinal stress.

Fluid-gas exchanges, fluid-silicone exchanges and gas-silicone exchanges can easily be optically monitored even in phakic eyes with the wide-angle lens.

9 Care and Maintenance

9.1 Removable accessories

The rubber cap on the adjustment knob is easy to fix and is always removable.

When disconnecting electrical connections, pull on the respective plug instead of the cable itself.

In order to disconnect the hand / foot switch, please unscrew its threaded plug connector and then pull the plug out of its socket.

9.2 Care, cleaning and desinfection

Attention

Disconnect the plug from the power supply before cleaning the unit.

Do not use aggressive cleaning agents that contain chlorine or solvents, nor abrasive or sharp-edged cleaning products to clean the unit .

Cleaning and disinfecting the housing

The outer surfaces of the unit can be cleaned by wiping with a damp cloth.

Wipe any residual particles using a mixture containing equal parts of spirits and distilled water, and add a dash of household washing up liquid.

A wiping disinfection of the SDI 4 is possible with the same disinfectants used for the microscope.

Only the electrically switchable versions SDI 4c and SDI 4e are splash water proof but may not be immersed in liquids.

A sterilization of the SDI 4 is not possible.

Cleaning the protective glasses (only for SDI 4c and SDI 4e)

Even slight soiling due to dust or fingerprints may reduce image quality.

The protective glass covers can be cleaned from the outside with a soft cloth or lens brush, using alcohol or a lens cleaning agent if necessary.

Sterilization of the rubber cap

If the rubber cap covering of the adjustment element shall be used, it is to be attached when sterile.

The rubber cap is steam autoclavable (134°C / 273° F).

Sterilization of wide angle contact lenses

Please observe the product information provided with these lenses since lenses have different sterilization instructions. Other sterilisation methods than indicated there may cause damage to the lenses.

10 Troubleshooting

Attention

If an error occurs which you are unable to correct by following the instructions below, label the device as "out of order" and contact our service department.

Troubleshooting guide - SDI 4

Fault	Possible Cause	Help
No reaction when hand-held pushbutton is used (hand-held pushbutton for SDI 4c only optional)	Hand-held pushbutton is not connected to SDI 4e No connection of the SDI 4e to the power supply Power failure or power outlet is not active These are not active when the sockets at the stand are in use	Establish the connection to the SDI 4e Establish the connection to the power supply Inform the in-house electrician Use the net plug adapter Use the mechanical adjusting element Activate the sockets in accordance with the instructions for the stand Ask the microscope manufacturer for assistance
The image is truncated	The SDI or other components are incorrectly mounted at an angle The optics of the SDI 4 are not in operating position (locking position)	Correct the assembly Switch in or out once more by electrical switch or the adjustment knob
Unclear image	The glass surfaces of the SDI 4, the contact lens or other parts of the optical system are soiled	Clean the glass surfaces
The SDI 4 or its fixtures wobble	The locking screws are loose	Tighten the locking screws
Fundus view is too narrow	Distance between ophthalmoscopic front lens and eye too large (only when using BIOM 4) Magnification of the microscope system to high	Carefully reduce the distance using the microscope fine focusing mechanism Reduce magnification of the microscope
Pronounced reflections on BIOM-front lens or contact lens	The microscope light is on	Turn the light off, illuminate only intraocular

11 Warranty and Service

11.1 Warranty

The device you have purchased is a high-quality OCULUS product. This device was carefully manufactured using quality materials and modern production methods. Prior to and while operating the device it is important that you observe the instruction manual and safety instructions.

The device carries a warranty to which you are entitled in accordance with the legal provisions.

If the unit is tampered with in any way by non-authorized persons, all warranty claims are rendered null and void, because improper modifications, maintenance and repairs can lead to considerable harzards for the user and the patient.

In the event of transport damage, we request that you notify the shipping company immediately and have the damage confirmed on the consignment note, to enable a proper claims settlement procedure.

Overall, the general terms and conditions of business and delivery apply as per the date of purchase.

11.2 Assumption of liability for functions and damage

OCULUS Optikgeraete GmbH will only accept responsibility for the safety, reliability and serviceability of the unit if the SDI 4 is used in compliance with the instructions contained in this instruction manual.

OCULUS Optikgeraete GmbH shall not assume any liability if assembly, extensions, adjustments, changes or repairs are carried out by unauthorised personnel, if the unit is maintained improperly or if it is handled incorrectly.

11.3 Manufacturer's and service addresses

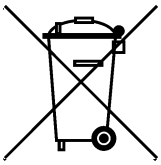
Our service department or authorised representatives will furnish you with additional information.

Manufacturer - Service Addresses:

Germany:

OCULUS Optikgeräte GmbH
Muenchholzhaeuser Str. 29
D - 35582 Wetzlar, Germany
Tel.: ++49 641/2005-0
Fax: ++49 641/2005-295
E-mail: sales@oculus.de

12 Disposal of Used Devices



In accordance with Directive 2002/96/EC of the European Parliament and the Council of 27 January 2003, and in accordance with German law governing the circulation, return and environmentally friendly disposal of used electrical and electronic devices, such appliances must be recycled and may not be discarded as household waste.

13 Declaration of Conformity

We declare under our sole responsibility that this product meets the fundamental requirements of Annex 1 of Directive 93/42/EEC of 14th June, 1993 for medical products.

Following harmonized standards were employed to verify the above mentioned requirements:

-DIN EN ISO 15004

CE

according to the regulations of MDD

Dipl.Ing. Rainer Kirchhübel

Management
OCULUS Optikgeräte GmbH

14 Order Information, Accessories and Replacement Parts

SDI 4 models

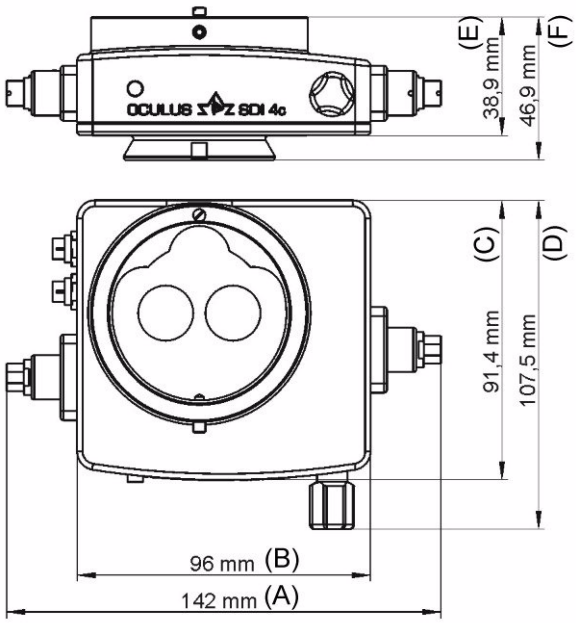
SDI models	Order number
■ SDI 4m	54302
■ SDI 4m (Leica version)	54312
■ SDI 4e	54300
■ SDI 4e (Leica version)	54310
■ SDI 4c	54320
■ SDI 4c (Leica version)	54330

Optional accessories for the SDI 4 models

Component	Order number
Rubber cap for star knob (5-pack)	54335
Hand-held pushbutton 5-pole	54882
Foot switch 5-pole	54883
Extension cord for switch	54885
Net plug adapter for SDI 4e / SDI 4c, 230V / 6V - European plug	54890
Net plug adapter for SDI 4e / SDI 4c, 230V / 6V - American, Asian plug	54891
Extension cord for power supply of SDI e	54899
Cable (Standard) for power supply, SDI e	54800 09 001
Securing device	54300-00-001
Hexagon screw driver	05490061
Dual switch adapter	54878

15 Technical Data

SDI 4c - dimensions



(A) Width
(B) Width of housing
(C) Depth of housing
(D) Depth
(E) Instalment heigth
(F) Height

fig. 15-1: Dimensions SDI 4c

SDI 4c Leica version

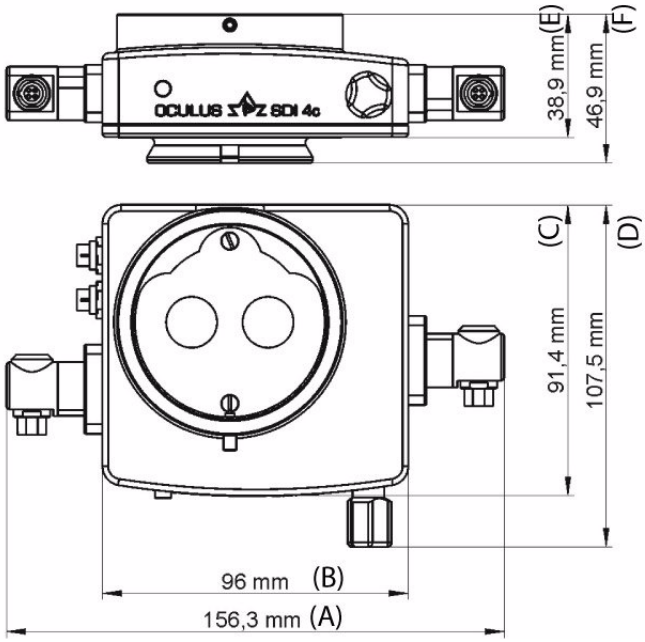


fig. 15-2: Dimensions SDI 4c - Leica version

SDI 4e and SDI 4m - Dimensions

Width	96 mm
Depth	91,4 mm
Height	38,9 mm

Classification according to IEC 60601 - 1

Type of protection against electrical shock	Protection class 2
Housing protection class	IP 64

Degree of protection when used in the presence of potentially explosive mixtures

This unit is not suitable for use in a potentially explosive atmosphere or in the presence of potentially explosive anaesthetic mixtures containing oxygen or nitreous oxide.

Ambient operating requirements

Temperature	+10 °C to +40 °C
Humidity	30% to 75%
Air pressure	700 hPa to 1060 hPa

Power supply

Power supply	6-15 V AC / DC 0,5 A

Operating mode

Operating mode	Temporary

Weight

SDI 4c	approx. 675 g
SDI 4e	approx. 600 g
SDI 4m	approx. 500 g

Ways of switching back and forth: SDI 4c

Combination footswitch (electrically via 5-pin plug)
Adjustment knob (manually, mechanically)

Ways of switching back and forth: SDI 4e

Hand-held pushbutton (electrically via 5-pin plug)
Foot switch (electrically via 5-pin plug)
Adjustment knob (manually, mechanically)

Ways of switching back and forth: SDI 4m

Adjustment knob (manually, mechanically)

Sterilization and disinfection procedures

Combination foot switch	wet disinfection
rubber cap for adjustment knob	steam autoclaving (at max. 134° C / 273° F)

Symbols on the instrument

The instruments meets the requirements of the specified standard

Follow the instruction manual

Type B application

IP 64 Type of device protection

The unit can be attached to the following microscopes:

- Zeiss:
  OPMI 1/6
  OPMI CS with Retrolux 1/3/CS
  OPMI CS with Retroskop 1/2/CS
  OPMI MDI/MDO/MDU
  OPMI VISU 150/ VISU 160
  OPMI VISU 200 / VISU 210
  OPMI Lumera
  OPMI Lumera T

- Leica:
  M500 / M501 / M620
  M650 / M690
  M820 / M840 / M841 / M844

- Moeller:
  Ophtamic 900 / Hi-R 900 / EOS 900

- Takagi:
  OM 18

- Topcon:
  OMS 600 / OMS 610 / OMS 650
  OMS 110
  OMS 710
  OMS 800 Standard / OMS 800 Pro

- Kaps:
  SOM